

TSCA HEALTH & SAFETY STUDY COVER SHEET

TSCA CBI STATUS:

X -CHECK IF THIS PAGE CONTAINS CONFIDENTIAL BUSINESS INFORMATION (CBI)

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1.0 SUBMISSION TYPE <i>X- Contains CBI</i> <input type="checkbox"/> 8(d) <input checked="" type="checkbox"/> 8(e) <input type="checkbox"/> FYI <input type="checkbox"/> 4 <input type="checkbox"/> OTHER: Specify _____ X- Initial Submission <input type="checkbox"/> Follow-up Submission - Final Report Submission Previous EPA Submission Number or Title if update or follow-up: _____ Docket Number, if any: # 8EHQ-0497-13919s <input type="checkbox"/> continuation sheet attached		
2.1 SUMMARY/ABSTRACT ATTACHED (may be required for 8(e): optional for §4, 8(d) & FYI) X - YES <input type="checkbox"/> NO	2.2 SUBMITTER TRACKING NUMBER OR INTERNAL ID Cert# P 917006678 97-2-11	2.3 FOR EPA USE ONLY
3.0 CHEMICAL/TEST SUBSTANCE IDENTITY <i>X-Contains CBI</i> <i>Reported Chemical Name (specify nomenclature if other than CAS name):</i> CAS#: 140923-25-7 Purity _____ % X - Single Ingredient <input type="checkbox"/> Commerical/Tech Grade <input type="checkbox"/> Mixture Trade Name: _____ Common Name: Amino acid amid carbamate <div style="text-align: center; font-weight: bold; font-size: 1.2em;">COMPANY SANITIZED</div>		
4.0 REPORT/STUDY TITLE <i>- Contains CBI</i> Results from Study of Chronic Toxicity and Carcinogenicity in Wistar Rats, Study # T1055425 <input type="checkbox"/> Continuation sheet attached <div style="text-align: right; font-weight: bold; font-size: 1.5em;">COMPANY SANITIZED</div>		
5.1 STUDY/TSCATS INDEXING TERMS [CHECK ONE] HEALTH EFFECTS (HE): <input checked="" type="checkbox"/> ENVIRONMENTAL EFFECTS (EE): _____ ENVIRONMENTAL FATE (EF): _____		
5.2 STUDY/TSCATS INDEXING TERMS (see instructions for 4 digit codes) STUDY TYPE: <u>CTCA</u> SUBJECT ORGANISM (HE, EE only): <u>RATS</u> ROUTE OF EXPOSURE (HE only): <u>ORAL</u> VEHICLE OF EXPOSURE HEonly): <u>FOOD</u> Other: <u>Experimental</u> Other: _____ Other: _____		
6.0 REPORT/STUDY INFORMATION <input type="checkbox"/> Contains CBI <input type="checkbox"/> Study is GLP Laboratory <u>Bayer AG -Wuppertal</u> Report/Study Date <u>3/25/97</u> Source of Data/Study Sponsor (if different than submitter) <u>Bayer AG</u> Number of pages <u>2</u> <input type="checkbox"/> continuation sheet attached		
7.0 SUBMITTER INFORMATION <input type="checkbox"/> Contains CBI Submitter: <u>Donald W. Lamb, Ph D</u> Title: <u>V. P., Prod. Safety & Reg. Affrs</u> Phone: <u>412-777-7431</u> Company Name: <u>Bayer Corporation</u> Company Address: <u>100 Bayer Road</u> <u>Pittsburgh, PA 15205-9741</u> Submitter Address (if different): _____ Technical Contact: <u>Donald W. Lamb, Ph.D</u> Phone: <u>(412)777-7431</u> <input type="checkbox"/> continuation sheet attached		
8.0 ADDITIONAL/OPTIONAL STUDY COMMENTS <input type="checkbox"/> Contains CBI The information being reported is a summary report on an experimental pesticide. (full report not completed yet) <input type="checkbox"/> continuation sheet attached		

Submitter Signature: Donald W Lamb

Date: 4/18/96

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9.0 CONTINUATION SHEET

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97-2-11

CONTINUED FROM COVER SHEET SECTION # 2.1

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Findings include uncommon/rare tumors in the uterus, urinary bladder, clitoral glands, and skeletal muscle.

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Adverse Effects and Scientific Evaluation

Compound:

Study Title: Study of Chronic Toxicity and Carcinogenicity in Wistar Rats

Author(s) : Dr. L. Schladt, Dr. E. Hartmann

Date : Tuesday, 25. March 1997 CAS #: 140923-25-7

Report No.: (study not yet reported) Guideline No.: 83.5

Study No. : T1055425

Purpose of the study: To establish a NOAEL for chronic toxicity and to investigate possible carcinogenic effects.

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Governing Agency For Reporting Purposes:

☐ EPA-FIFRA ☒ EPA-TSCA ☐ FDA

☐ SPECIAL REVIEW ☐ DATA-CALL-IN ☐ REREGISTRATION

Discussion of Reported Effects:

In this study, groups of Wistar rats (50 animals/dose/sex) were exposed over a two year period to _____ in the diet using nominal concentrations of 0 - 500 - 5000 - 20000 ppm.

Body weight development of males was temporarily slightly retarded in the dose group 20000 ppm. The differences from the control animals were mostly significant and were maximally 8%. Beginning from week 61 the differences to control values did not longer achieve statistical significance and during the last weeks of the study body weights were practically identical to

Adverse Effects and Scientific Evaluation

those of the control animals. In 20000 ppm-females the differences to controls were mostly statistically significant during the study period. The difference to control was maximally 12%. Beginning with week 12 statistical significant differences occurred also in 5000 ppm-females (maximally 7%).

Histopathological investigations showed that hepatocellular hypertrophy occurred in higher frequency in females which received 5000 ppm or 20000 ppm.

Furthermore, these investigations revealed uncommon/rare tumors:

In the uterus of treated females an increased frequency of malignant mixed Muellerian tumors was seen (tumor distribution in ascending order of dose: 0-0-1-2).

Transitional cell papillomas of the urinary bladder were observed in two females of the high dose group (0-0-0-2).

Squamous cell carcinomas of the clitoral glands occurred in two females of the 20000 ppm group (0-0-0-2).

Malignant neoplasms of the skeletal system occurred in four males of the 20000 ppm group (three osteosarcomas, one chondrosarcoma; 0-0-0-4).

Furthermore, the incidence of adenomas of the thyroid gland was statistically significantly increased in 20000 ppm females (0-0-1-2-). On the other hand there was a statistically significant decline in the number of mammary gland adenocarcinomas at 20000 ppm (6-3-2-0)

Dr. L. Schladt
Study Director

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Bayer Corporation
100 Bayer Road
Pittsburgh, PA 15205 9741

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Attn: Section 8(e) Coordinator
Office of Toxic Substances
U.S. EPA
401 M Street, SW
Washington, DC 20460

